Phthalate Esters Category – Comments of Environmental Defense

(Submitted via Internet 7/1/02)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for Phthalate Esters Category.

Exxon Biomedical Sciences prepared the phthalate ester test plan for the American Chemistry Council. The phthalate esters have a wide array of uses although the primary use is as a plasticizer for PVC tubing and medical devices. A recent study on phthalate ester metabolites in human urine published by CDC and NIEHS concluded that almost everyone in the U.S. is exposed to phthalate esters, including many of the 18 phthalates covered in this test plan, in their day-to-day living.

We agree with the sponsor that no new studies are needed as the database on the phthalates is significant (particularly in the context of the screening-level requirements of the HPV program). They have been subjected to considerable scientific scrutiny over the last 30 years and although many questions remain, the available information exceeds that required by the HPV program. These studies include investigations on health effects in people and experimental animals, as well as numerous studies on the mechanism of action in various target tissues such as the liver and reproductive tract. The NTP Center for the Evaluation of Risks to Human Reproduction recently released a comprehensive report on 7 of the phthalate esters included in this test plan. This report integrates diverse data from human studies, experimental studies in animals and mechanistic studies into an overall assessment and provides a valuable and objective reference on the reproductive and developmental effects of the phthalate esters. Because of their widespread use, phthalate esters are regulated (though not necessarily comprehensively so) by EPA, FDA, and the Consumer Products Safety Commission.

We agree with the sponsor's two central conclusions presented in the test plan. First, it makes good sense to subcategorize the 18 phthalates into 3 groups: low molecular weight, transitional, and high molecular weight. However, we caution against overly simplistic conclusions that only the transitional phthalates pose human health risks. While the available data indicate that the transitional phthalates, like DEHP, are the most toxic, the others are not devoid of biological activity. We also caution against some of the statements made in the text that some of the health effects reported in experimental animals are not relevant to humans. This represents a non-reviewable risk assessment because the data and information needed to support it are not present in the test plan or robust summaries. Furthermore, it is not the intent of the HPV Challenge Program to conduct risk assessments. We recommend that the HPV documents simply refer to health assessments made by EPA, FDA, CPSC, NTP, OECD and others for information on the results and status of ongoing risk assessments by those agencies.

We agree with the second central conclusion that reproductive and developmental effects pose the greatest health threat for the phthalates and that the available scientific information far exceeds requirements of the HPV Program. Thus, we concur that no additional testing is needed under the HPV initiative.

Thank you for this opportunity to comment.

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